



DECLARATION OF CONFORMITY

**Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC**

Manufacturer: Nanning TECBOD Biological Technology Co.,Ltd

Address: Room 601 Floor 6, B2 Building, No 19 Guokai Dadao,Nanning , Guangxi,
P.R.China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam,Netherlands

Product Name: Medical Protective Clothing

Specification: Conjoined coverall/XS、S、M、L、XL、XXL

Split overalls/XS、S、M、L、XL、XXL

Product Name: Disposable isolation gown

Specification: Conjoined coverall/M、L、XL、XXL、XXXL (Full body)

Split overalls/XS、S、M、L、XL、XXL

Hooded/XS/160、S/165、M/170、L/175、XL/180、XXL/185

Product Name: Single-use medical protective overboot

Specification: Normal type/L (30cm~40cm) ×W (10cm~30cm)

Tall type/L (30cm~40cm) ×W (10cm~30cm) ×H (30cm~60cm)

Classification: Class I (MDD, Annex IX)

Conformity Assessment

Procedure: Annex VII of Medical Device Directive(93/42/EEC)

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive (93/42/EEC) including Directive 2007/47/EC and the following harmonized standards.

*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008+A1:2013

ISO 10993-1:2018



Authorized Signature (S)

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 14126:2003+AC:2004

EN 13795:2011+A1:2013

Signature: _____

Name/ Position: Lei Zhen / GM

Date: 2020. 4. 29

Place: Nanning City/ China



*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

Sungo
gold service

Lei Zhen

Authorized Signature (S)